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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,315	07/14/2003	Moshe Rosenberg	309J-000310US	7949

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EXAMINER	
MERCIER, MELISSA S	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/620,315	ROSENBERG ET AL.	
	Examiner	Art Unit	
	Melissa S. Mercier	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15, 17-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15, 17-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Applicants Remarks and Amended Claims filed January 22, 2007 is acknowledged. Applicants have cancelled claims 16 and 27-66. Claims 1-15 and 17-26 are pending in this application.

Claim Rejections - 35 USC § 112

Claims 1-15 and 17-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The exclusion of protein cross-linking by formaldehyde, gluteraldehyde, or other aldehydes is new matter. Applicant point to paragraphs 0008 and 0010 for support to the exclusion of these compounds, however, paragraph 0010 discloses supplements can be protected to some extent by using the fatty acid calcium salts or formaldehyde cross linked capsule. This is a new matter rejection.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 12-13, 15, 17-18, and 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perrier et al. (US Patent 5,912,016).

Perrier discloses particles comprise, at least on the surface, a wall formed of plant proteins cross linked particularly by means of interfacial cross linking between the plant proteins and an acrylating polyfunctional cross linking agent comprising at least two acrylating groups, covalent bonds being formed between the acrylatable groups of the proteins and the acryl groups of the acrylating polyfunctional crosslinking agent. These particles are used for the manufacture of a cosmetic, pharmaceutical, dermatological or food composition (abstract). The interfacial cross-linking occurs at the interface of the phases of an emulsion, including oil-in-water type emulsions (column 3, lines 39-41). The plant proteins include soya and cereal proteins (column 5,lines 50-57). A hydrophobic phase containing a polyfunctional cross linking agent is emulsified in an

aqueous phase containing plant proteins and at least one carboxylic acid salt, used as a continuous phase. A membrane forms around the dispersed hydrophobic droplets to give particles with hydrophobic contents (column 4, lines 14-26). This solution is able to prepare particles whose size can be adjusted at will, particularly over a range of dimensions from a nanometer to a few millimeters, especially from about 10 nanometers to about 3 mm (column 3. lines 11-15). The aqueous solution used to dissolve the plant proteins contained in the pulverulent preparations is an aqueous buffer solution with a pH of between about 4.5 and about 8 (column 5, lines 62-65). The pH is obtained with the use of an alkali metal salt of a carboxylic acid, particularly sodium (column 5, line 66-column 6, line 5). The insoluble lipophilic substance to be incorporated into the aqueous phase, into the hydrophobic phase or into both phases can also be present in the bulk of the particles and/or adsorbed on the surface of these particles (column 6, lines 19-31). The particles may encapsulate substances, particularly active principles, including lipophilic active principles such as vegetable, mineral or synthetic oil, vitamin A and vitamin E derivatives, etc., and hydrophilic active principles such as plant extracts, ascorbic acid, vitamin C PMG, glucose, organic pigments and inorganic pigments (column 8, lines 35-45). The insoluble fatty acids salts which may be used include calcium, magnesium, strontium, and barium salts of carboxylic acids with a number of carbons equal to or greater than 12, such as oleic and linoleic acids (column 6, lines 32-36). The concentration of plant protein in the aqueous phase is between 0.5-5% by weight (column 6, lines 11-13). It is also possible to

incorporate various substances into the suspension including sugars, such as glucose (column 8, lines 22-26).

The instant claims differ from the references only in the specific percentage selected for the compositions. However, It would have been deemed prima Facie obvious to one having ordinary skill in the art at the time of the invention to optimize the percentage of plant protein and solids, reducing sugars and water to prepare a composition containing for the encapsulation of supplemental materials suitable for animal ingestion because the determination of a specific percentage having the optimum therapeutic effect is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as Whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

Claims 9-10, 17-18, and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perrier et al. (US Patent 5,912,016) in view of Richardson (US Patent 5,143,737).

Perrier's teachings are discussed above and applied in the same manner.

Perrier does not teach a lipid containing 10-50% conjugated linoleic acid.

Richardson teaches a lipid encapsulated feed supplement and process for making the same. The Richardson reference is silent as to the whether the linoleic acid used in their compositions is conjugated or not. Conjugated linoleic acid is found in dairy

products and meat sources. Richardson teaches the use of whey protein, which is a dairy product.

Regarding Claims 17-18 and 24, Richardson teaches, "an unsaturated lipid is encapsulated with protein, such as whey protein concentrate with includes the reducing sugar lactose, preparing an emulsion of the encapsulating agent, combining and mixing the food and the emulsion, maintaining the emulsion, naturally cross linking the emulsion and recovering the encapsulated food. Preferably the food is a mono- or polyunsaturated lipid, or an unsaturated animal or vegetable fat or oil. Especially useful are compositions of oleic acid, linoleic acids and mixtures thereof" (column 5, lines 37-53). Example 1 of Richardson further discloses the use of sodium hydroxide ((Example 1, column 4)

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Rawlings with the teachings of Richardson in order to obtain a cattle feed composition capable of "providing a higher level of unsaturated fat and less saturated fat" (Richardson abstract). Richardson additionally teaches "protection of unsaturated dietary fat from the digestive action of the rumen microbes found in the digestive tract of ruminant animals is primarily advantageous because the polyunsaturated fats are liberated for absorption and transfer to the milk resulting in increased polyunsaturated fatty acid content. It also provides a higher energy density feed source" (Richardson, column 3, lines 1-10).

The applicant would have a reasonable expectation of success for preparing a composite gel suitable for ingestion, because both the Perrier and Richardson patents teach a composition for the same purpose.

The instant claims differ from the references only in the specific percentage selected for the compositions. However, It would have been deemed prima Facie obvious to one having ordinary skill in the art at the time of the invention to optimize the percentage of plant protein and solids, reducing sugars and water to prepare a composition containing for the encapsulation of supplemental materials suitable for animal ingestion because the determination of a specific percentage having the optimum therapeutic effect is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as Whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-8, 11, 14-15, 17-18, and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dollat et al. (US Patent 5,500,415) in view of Perrier et al. (US Patent 5,912,016).

Dollat discloses a process for the preparation of spherules and emulsions containing spherules. A primary oil-in-water emulsion is formed containing particles comprising one or more active principles in oily form suspended in water. The water optionally containing at least one protein. The particles have a mean diameter of about 1um. If protein is contained in the emulsion can be cross-linked (abstract). Examples of

actives include vitamins, caratenoids, and enzymes (column 1, lines 11-20). The oils may be chosen from vegetable or animal oils such as groundnut, sunflower, rapeseed, or cod liver oil (column 2, lines 54-61). Dollat discloses it is preferable to use gelatin as a protein source (column 3, lines 25-30). The protein cross-linking agent used can include acetoaldehyde, gluteraldehyde, and glyoxal (column 4, lines 7-10). The aqueous protein solution comprises approximately 10-60% by weight protein, and approximately 10-60% by eight sugars including glucose, lactose, fructose, sucrose and maltodextrin (column 3, lines 30-35). A surfactant may also be incorporated into the composition including an alkali metal or alkaline earth metal including sodium or calcium 2-stearoyllactate (column 3, lines 9-14). The process for making the emulsion is carried out at a temperature higher than the gel point, however, it is the examiners position that once the emulsion is allowed the cool, a gel would form.

Dollat does not disclose cross-linking of proteins without formaldehyde, gluteraldehyde, or other aldehydes.

Perrier's teachings are described above and applied in the same manner.

Perrier discloses plant proteins cross linked particularly by means of interfacial cross linking between the plant proteins and an acryl ting polyfunctional cross linking agent comprising at least two acrylating groups, covalent bonds being formed between the acrylatable groups of the proteins and the acyl groups of the acylating polyfunctional cross linking agent (abstract).

It would have been obvious to a person of ordinary skill in the art to substitute the cross linking agents disclosed by Perrier into the composition taught by Dollat. Applicant

is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

Additionally, the instant claims differ from the references only in the specific percentage selected for the compositions. However, It would have been deemed prima Facie obvious to one having ordinary skill in the art at the time of the invention to optimize the percentage of water to prepare a composition containing for the encapsulation of supplemental materials suitable for animal ingestion because the determination of a specific percentage having the optimum viscosity is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as Whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

Claims 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Perrier et al. (US 5,912,016), or in the alternative Dollat et al. (US Patent 5,500,415) in view of Winowiski (US Patent 4,957,748).

The teachings of Perrier and Dollat are discussed above and applied in the same manner.

Neither Perrier, nor Dollat disclose the proteins being cross-linked by Maillard reactions chemistries with reducing sugars.

Winowiski discloses a ruminant feed composition comprising protein and a reducing sugar mixed in quantities suitable for the Maillard reaction (abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used the protein and reducing sugar proportions disclosed by Winowiski in order to provide a technique for utilizing a reducing sugar and or mixtures of reducing sugars to increase the efficiency of utilization of fed proteins to animals (column 2, lines 60-64). One of ordinary skill would have a reasonable expectations of success since both Perrier and Dollat disclose the use of proteins and reducing sugars, and Winowiski discloses Maillard reactions are well know and the pH, temperature, moisture and time required to carry out the reaction to optimum extent can be determined with little experimentation (column 6, lines 50-55).

Response to Arguments

Applicant's arguments with respect to claims 1-15 and 17-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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